

DETAILED ACTION

1. This action is in response to the papers filed September 9, 2009. Currently, claims 1-4, 34-39, 42, 43, 47, 49 and 50 are pending. Claims 1-3, 34-39, 42, 49 have been withdrawn as drawn to non-elected subject matter.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2009 has been entered.
3. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
4. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Election/Restrictions

5. Applicant's election with traverse of Group II, Claims 4-5, 26, 31, 41, 43-46 in the paper filed June 30, 2008 is acknowledged.

The examiner thanks applicants for pointing out that Claims 43-46 were inadvertently grouped with Group I when they should be grouped with elected Group II. Claims 43-46 are hereby placed in Group II.

Moreover, Claim 31 which depends on Claim 31 is within Group II.

The response further asserts that restriction to a single polymorphism is unduly restrictive. The response asserts that there would not be a serious search and examination burden to the Office and request reconsideration of the restriction requirement to include at least all of the variants to the EMP2B gene identified in the specification. This argument has been reviewed, but is deemed not persuasive. Current Claim 4 appears to be drawn to a generic linking claim. In the event that an allowable generic linking claims is found, the examiner will consider rejoinder of the variants encompassed within the scope of the allowable generic linking claim. However, no allowable generic or linking claim has been presented at this time.

Applicants argue that they are entitled to claim the entire genus of variations of the EPM2B gene that are associated with Lafora's disease. The response states that the members of the genus have a substantial common structure, namely the nucleic acid sequence of EPM2B, as set forth in SEQ ID NO: 1. This argument has been reviewed but is not persuasive. The "substantial common core" is known in the art, namely the "wild type" EPM2B gene is known in the art. It is the differences between the common core that applicants (i.e. the variants) are relying upon for patentability and not the common core structure that was known in the art. Thus, the variants are drawn to what is different from the common core and not the commonality of the core.

Claims 1-3, 6-25, 31, 34-39, 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 1-3, 6-25, 31, 34-39, 42 have drawn to an invention nonelected with traverse in the paper filed June 30, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

6. This application is a 371 of PCT/CA04/01449, July 30, 2004 which claims priority to 60/491,968, filed August 4, 2003.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

a. The specification contains a list on pages 56-60 of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) It is unclear whether Claim 4 is directed to a method of detecting the presence of or predisposition to Lafora's disease in a human or whether the claim is merely drawn to the detection of a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO: 1. The preamble of the claim is directed to detecting the presence of or predisposition to Lafora's disease however the final step is directed to the detection of a C to G change. The claim could be amended to include a wherein clause, for example "wherein the presence of a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO: 1 indicates the presence or predisposition to Lafora's disease in the human."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 4, 43, 47, 50 are rejected under 35 U.S.C. 102(a) as being anticipated by Chan et al. (Nature Genetics, Vol. 35, No. 2, pages 125-127, October 2003).

It is noted that the authorship of the Chan et al. reference is distinct from the inventorship of the instant application and that this rejection may be overcome by the filing of a 132 Katz-type declaration.

It is noted that SEQ ID NO: 1 from the provisional application and SEQ ID NO: 1 of the instant application are different. SEQ ID NO: 1 from the provisional application is 2134 nts in length, the instant SEQ ID NO: 1 is 2120. Thus, the instant SEQ ID NO: 1 was not disclosed in the provisional application and the application is awarded priority of the instant filing date.

Chan teaches mutations in the EPM2B gene cause Lafora progressive myoclonus epilepsy. Chan teaches screening by sequencing DNA from individuals homozygous with respect to markers in the EPM2B critical region (page 125, col. 2). Moreover, Chan teaches sequencing EPM2B in a cohort of 34 probands with Lafora disease and identified 17 different DNA sequence alterations in 26 families which were not present in 100 control chromosomes. Among these polymorphisms was the mutation at 205 (see Table 1). Chan teaches that the accession number BK001510 was used for EPM2B. This sequence comprises SEQ ID NO: 1 of the instant application, required by the instant claims.

10. Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Blakey et al. (Genbank Number gi13509424, April 30, 2001).

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Blakey teaches a DNA sequence from the homo sapiens chromosome 6 clone RP11-204B7 which comprises SEQ ID NO: 1. Blakey teaches detecting the presence of EPM2B gene by analyzing a test sample obtained from the human for the presence of a nucleic acid comprising SEQ ID NO:1.

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Query Match          100.0%; Score 2120; DB 5; Length 147927;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 2120; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1  ATGGCGGCCGAAGCCTCGGAGAGCGGGCCAGCGCTGCATGAGCTCATGCGCGAGGCGGAG  60
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 85161 ATGGCGGCCGAAGCCTCGGAGAGCGGGCCAGCGCTGCATGAGCTCATGCGCGAGGCGGAG  85102

Qy      61  ATCAGCCTGCTCGAGTGCAAGGTGTGCTTTGAGAAGTTTGGCCACCGGCAGCAGCGGCGC  120
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 85101 ATCAGCCTGCTCGAGTGCAAGGTGTGCTTTGAGAAGTTTGGCCACCGGCAGCAGCGGCGC  85042

Qy     121  CCGCGCAACCTGTCTGCGGCCACGTGGTCTGCCTGGCCTGCGTGGCCGCCCTGGCGCAC  180
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 85041 CCGCGCAACCTGTCTGCGGCCACGTGGTCTGCCTGGCCTGCGTGGCCGCCCTGGCGCAC  84982

Qy     181  CCGCGCACTCTGGCCCTCGAGTGCCCATCTCTGCAGGCGAGCTTGCCGGGGCTGCGACACC  240
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84981 CCGCGCACTCTGGCCCTCGAGTGCCCATCTCTGCAGGCGAGCTTGCCGGGGCTGCGACACC  84922

Qy     241  AGCGACTGCCTGCCGGTGCTGCACCTCATAGAGCTCCTGGGCTCAGCGCTTCGCCAGTCC  300
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84921 AGCGACTGCCTGCCGGTGCTGCACCTCATAGAGCTCCTGGGCTCAGCGCTTCGCCAGTCC  84862

Qy     301  CCGGCCGCCCATCGCGCCGCCCCAGCGCCCCGGAGCCCTCACCTGCCACCACACCTTC  360
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84861 CCGGCCGCCCATCGCGCCGCCCCAGCGCCCCGGAGCCCTCACCTGCCACCACACCTTC  84802

Qy     361  GGCGGCTGGGGGACCCTGGTCAACCCACCGGACTGGCGCTTTGTCCAAGACGGGGCGT  420
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84801 GGCGGCTGGGGGACCCTGGTCAACCCACCGGACTGGCGCTTTGTCCAAGACGGGGCGT  84742

Qy     421  GTCGTGGTGGTGCACGACGGCAGGAGCGGTGTCAAGATTTTGAAGGAGGAGGATGC  480
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Db 84741 GTCGTGGTGGTGCACGACGGCAGGAGCGGTGTCAAGATTTTGAAGGAGGAGGATGC  84682

Qy     481  GCGCATCAGTTTGGAGAGAAGGGGGACGCTGCCCAAGACATTAGGTACCCTGTGGATGTC  540
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84681 GCGCATCAGTTTGGAGAGAAGGGGGACGCTGCCCAAGACATTAGGTACCCTGTGGATGTC  84622

Qy     541  ACCATCACCAACGACTGCCATGTGGTTGTCACTGACCGGGCGATCGCTCCATCAAAGTG  600
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84621 ACCATCACCAACGACTGCCATGTGGTTGTCACTGACCGGGCGATCGCTCCATCAAAGTG  84562

Qy     601  TTTGATTTTTTTGGCCAGATCAAGCTTGTCAATTGGAGGCCAATTCTCCTTACCTTGGGGT  660
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84561 TTTGATTTTTTTGGCCAGATCAAGCTTGTCAATTGGAGGCCAATTCTCCTTACCTTGGGGT  84502

Qy     661  GTGAGACCACCCCTCAGAATGGGATTGTGGTAACTGATGCGGAGGCAGGGTCCCTGCAC  720
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84501 GTGAGACCACCCCTCAGAATGGGATTGTGGTAACTGATGCGGAGGCAGGGTCCCTGCAC  84442

Qy     721  CTCCTGGACGTCGACTTCGCGGAAGGGGTCTTCGGAGAACTGAAAGGTTGCAAGCTCAT  780
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 84441 CTCCTGGACGTCGACTTCGCGGAAGGGGTCTTCGGAGAACTGAAAGGTTGCAAGCTCAT  84382
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Qy 781 CTGTGCAATCCCCGAGGGGTGGCAGTGTCTTGGCTCACCGGGGCCATTGCGGTCTGGAG 840
| | | | |
Db 84381 CTGTGCAATCCCCGAGGGGTGGCAGTGTCTTGGCTCACCGGGGCCATTGCGGTCTGGAG 84322

Qy 841 CACCCCTGGCCCTGGGGACTGGGGTTTGCAGCACCAGGGTGAAAGTGTCTAGCTCAAGT 900
| | | | |
Db 84321 CACCCCTGGCCCTGGGGACTGGGGTTTGCAGCACCAGGGTGAAAGTGTCTAGCTCAAGT 84262

Qy 901 ATGCAGCTTGTGCGCCAAGTGGATACCTTTGGGCTGAGCCTCTACTTTCCCTCCAAAATA 960
| | | | |
Db 84261 ATGCAGCTTGTGCGCCAAGTGGATACCTTTGGGCTGAGCCTCTACTTTCCCTCCAAAATA 84202

Qy 961 ACTGCCTCCGCTGTGACCTTTGATCACCAGGGAATGTGATTGTTGCAGATACATCTGGT 1020
| | | | |
Db 84201 ACTGCCTCCGCTGTGACCTTTGATCACCAGGGAATGTGATTGTTGCAGATACATCTGGT 84142

Qy 1021 CCAGCTATCCTTTGCTTAGGAAAACCTGAGGAGTTTCCAGTACCGAAGCCCATGGTCACT 1080
| | | | |
Db 84141 CCAGCTATCCTTTGCTTAGGAAAACCTGAGGAGTTTCCAGTACCGAAGCCCATGGTCACT 84082

Qy 1081 CATGGTCTTTCGCATCCTGTGGCTCTTACCTTCACCAAGGAGAATTCTCTTCTGTGCTG 1140
| | | | |
Db 84081 CATGGTCTTTCGCATCCTGTGGCTCTTACCTTCACCAAGGAGAATTCTCTTCTGTGCTG 84022

Qy 1141 GACACAGCATCTCATTCTATAAAAGTCTATAAAGTTGACTGGGGGTGATGGGCTGGGGTG 1200
| | | | |
Db 84021 GACACAGCATCTCATTCTATAAAAGTCTATAAAGTTGACTGGGGGTGATGGGCTGGGGTG 83962

Qy 1201 GGTCCCTGGAATCAGAAGCACTAGTGCTGCCATTAATGAATTGTTTAACCTGGATAAGT 1260
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Db 83961 GGTCCCTGGAATCAGAAGCACTAGTGCTGCCATTAATGAATTGTTTAACCTGGATAAGT 83902

Qy 1261 CACTTAACTCATCTATCCAGGCAGGGATAATTAAAACCATCTGGCAGACTTACAAAGCT 1320
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Db 83901 CACTTAACTCATCTATCCAGGCAGGGATAATTAAAACCATCTGGCAGACTTACAAAGCT 83842

Qy 1321 TGGGACAGTTATTGGAGATTAATCTACCATTTATTGAATGCATACTCTGTGCAAGGAAAT 1380
| | | | |
Db 83841 TGGGACAGTTATTGGAGATTAATCTACCATTTATTGAATGCATACTCTGTGCAAGGAAAT 83782

Qy 1381 TTGCAAATATTAGCTTATTTAATCTGTACTATCCAGTGAGGTAATTTCTTCCCCCAAG 1440
| | | | |
Db 83781 TTGCAAATATTAGCTTATTTAATCTGTACTATCCAGTGAGGTAATTTCTTCCCCCAAG 83722

Qy 1441 ATAGAGTCAAGCTCTGTCAACCAGGCTGGAGTGCAGAAGCATGATCACAGCTCACTACAG 1500
| | | | |
Db 83721 ATAGAGTCAAGCTCTGTCAACCAGGCTGGAGTGCAGAAGCATGATCACAGCTCACTACAG 83662

Qy 1501 TTTCAACGTCCCCCGCTCAGGTGGTCCTTCCACCTCAGCCTCCCAAGTAGCTGGGACCAC 1560
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Db 83661 TTTCAACGTCCCCCGCTCAGGTGGTCCTTCCACCTCAGCCTCCCAAGTAGCTGGGACCAC 83602

Qy 1561 AAGTGTGCATTACCACACTCAGCTAATTTTGTATTTTGGCAGAGATGGGGTTTCACCAT 1620
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Db 83601 AAGTGTGCATTACCACACTCAGCTAATTTTGTATTTTGGCAGAGATGGGGTTTCACCAT 83542

Qy 1621 GTTGCCAGGCTGGTCTCAAACCTCCTGAGTTCAAGCAATCCACCTTCCTCGGCCTCCCAA 1680
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Db 83541 GTTGCCAGGCTGGTCTCAAACCTCCTGAGTTCAAGCAATCCACCTTCCTCGGCCTCCCAA 83482

Qy 1681 AGTACTAGGAGTACAGGCATAGCCACTTGCTCAGCCATAATTTTATTATTAATCTCATT 1740
| | | | |
Db 83481 AGTACTAGGAGTACAGGCATAGCCACTTGCTCAGCCATAATTTTATTATTAATCTCATT 83422

Qy 1741 GTACAAGTGAGAAAACCTGAGACCCAGAGAGCTTAAGTGACTTCCTCGAGGTCATAGTTAC 1800
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Db      83421  GTACAAGTGAGAAAAGTGAAGACCCAGAGAGCTTAAGTGACTTCCTCGAGGTCATAGTTAC 83362
Qy      1801  TTACTGCCTTAGTCCCAATTTGAATTCAATTCTGATTCCAAATAAGTTGCGCTTAAATAA 1860
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Db      83361  TTACTGCCTTAGTCCCAATTTGAATTCAATTCTGATTCCAAATAAGTTGCGCTTAAATAA 83302
Qy      1861  GACAACAGATGTGGGAAAAATATGTGAATGTGTAGTGTGCTATGTGTACTGTCTTTACA 1920
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Db      83301  GACAACAGATGTGGGAAAAATATGTGAATGTGTAGTGTGCTATGTGTACTGTCTTTACA 83242
Qy      1921  AGTAGCTAATTATTTTAGCACAAAGATGTGCAAGAAAGGAGACTTTATGGAGAGTTCAG 1980
          |||||
Db      83241  AGTAGCTAATTATTTTAGCACAAAGATGTGCAAGAAAGGAGACTTTATGGAGAGTTCAG 83182
Qy      1981  GAGAAAAAGGATTTTGTGGTGGCCATCACTTTTCATTCAATTTGCGACTGCTCTGATGGCA 2040
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Db      83181  GAGAAAAAGGATTTTGTGGTGGCCATCACTTTTCATTCAATTTGCGACTGCTCTGATGGCA 83122
Qy      2041  CATTAGATGAAGTTACTGTTGATCCTGAGTTACGTGAATAAGAAAAACAATTGAACTGCT 2100
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Db      83121  CATTAGATGAAGTTACTGTTGATCCTGAGTTACGTGAATAAGAAAAACAATTGAACTGCT 83062
Qy      2101  TATTAAAAAAGTAAACATGT 2120
          |||||
Db      83061  TATTAAAAAAGTAAACATGT 83042

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Conclusion

11. No claims allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

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/Jeanine Goldberg/

Primary Examiner

November 25, 2009